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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,633	04/05/2004	Steven Bruce Puntenney		7078
36328	7590	09/28/2006	EXAMINER	
OMNIGEN RESEARCH, L.L.C. 738 CORSAIR DRIVE INDEPENDENCE, OR 97351-9434				FERNANDEZ, SUSAN EMILY
		ART UNIT		PAPER NUMBER
		1651		

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
10/829,633	PUNTENNEY ET AL.	
Examiner	Art Unit	
Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-30 is/are rejected.
- 7) Claim(s) 1 and 10 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

The preliminary amendment filed December 28, 2004, has been received and entered.

Claims 1-30 are pending and are examined on the merits.

Claim Objections

Claims 1 and 10 are objected to because of the following informalities: Claim 1 recites “is admixed” which is grammatically incorrect in its context. It is suggested that “is” in this recitation be deleted. Claim 10 recites “Claim2,” which should be replaced with “Claim 2.” Appropriate correction is required.

Applicant is advised that should claim 16 be found allowable, claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is rendered indefinite by the phrase, "the mineral clay product", which lacks antecedent basis. Parent claim 1 does not recite a "mineral clay product". Thus, claim 21 is rejected under 35 U.S.C. 112, second paragraph. It is suggested that the phrase, "the mineral clay product", be replaced with "the mineral clay".

Claims 25-28 are indefinite because they recite the phrase, "the diatomaceous earth", which lacks antecedent basis. Parent claim 1 recites a calcined diatomaceous earth, and not a diatomaceous earth. Thus, claims 25-28 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howes et al. (US 6,045,834) in view of Kessler et al. (Journal of Biological Chemistry, 1959, 234(9): 2281-2285), Kofod et al. (US 5,871,966), and Urman et al. (US 4,729, 902).

Howes et al. discloses compositions comprising yeast cell wall extract and a mineral clay which may be admixed with animal feeds (column 2, lines 62-65). The mineral clay that may be included in the composition include zeolite, bentonite, aluminosilicate, or mixtures thereof (see claim 8). Additionally, Howes et al. discusses the previous use of montmorillonite clay in animal feeds (column 2, lines 25-30). The yeast used to obtain the cell wall extract is preferably *Saccharomyces cerevisiae*. Howes et al. indicates that the yeast extract may be obtained by autolysis (column 3, lines 59-61).

The composition taught by Howes et al. "...can be fed to any animal including, but not limited to, avian, bovine,...,ovine..." (column 3, lines 20-22), which meets the limitations recited in instant claims 5-20. When admixed with animal feed, the composition decreases "absorption or uptake of the mycotoxins by the affected animal, thereby improving performance and health, and reducing the incidence of mycotoxin-associated diseases" (column 3, lines 23-29). Note that immunosuppression is one of the chronic symptoms of mycotoxicosis (a mycotoxin-associated disease) (column 2, lines 6-7). Therefore, the innate immune system of any animal is augmented by the administration of the Howes composition and thereby, in an animal fed the Howes composition, reduces susceptibility to an infection. Moreover, the augmentation of the innate immune system inherently shows an augmentation of L-selectin and interleukin-1 β .

Howes et al. does not expressly disclose the inclusion of beta-glucans, glucomannan, beta-1,3(4)-endoglucanohydrolase, and calcined diatomaceous earth in the composition, in the ratios recited in claims 26 and 27. Additionally, Howes et al. does not disclose the amount of composition admixed to animal feed as recited in claim 28. Finally, the reference does not teach the inhibition of fungal growth in the food, feedstuff or digesta of the mammalian and avian species by the composition.

Kessler et al. discloses that baker's yeast (*Saccharomyces cerevisiae*) contains glucans and glucomannan (page 2285, "Summary").

Kofod et al. discloses that endo-1,3(4)-beta-glucanases (E.C. 3.2.1.6), which are beta-1,3(4)-endoglucanohydrolases, catalyze the hydrolysis of certain linkages in glucans which are major components of fungal cells (column 1, lines 24-29). Kofod et al. notes that *Trichoderma longibrachiatum* is "known to produce enzymes exhibiting endo-1,3(4)-beta-glucanase activity" (column 1, lines 64-67). Kofod et al. specifically teaches a novel endo-1,3(4)-beta-glucanase which may be added to food or feed in order to "improve the feed-uptake and/or digestibility" (column 9, lines 18-21). Moreover, the enzyme may be used as an anti-fungal agent (column 9, lines 52-53).

Urman et al. discloses an animal feed supplement which comprises of calcined diatomaceous earth (column 3, lines 9-13). Furthermore, Urmann notes that calcined diatomaceous earth (calcined up to 1300°F/704°C) "eliminates fungus" (column 6, lines 10-14).

At the time the invention was made, it would have been obvious to have inferred that the composition taught by Howes et al. contained beta-glucans and glucomannan. One of ordinary

skill in the art would have concluded this since yeast cell walls contain beta-glucans and glucomannan, as taught by Kessler et al.

Additionally, it would have been obvious to have included endo-1,3(4)-beta-glucanases and calcined diatomaceous earth in the composition taught by Howes et al. One of ordinary skill in the art would have been motivated to have included endo-1,3(4)-beta-glucanases since these enzymes would have resulted in a more digestible animal feed. Moreover, these enzymes would have contributed to the function of the Howes composition in mycotoxin reduction by reducing the presence of the mycotoxin source (fungi). Similarly, calcined diatomaceous earth would have contributed to the reduction of myotoxin by eliminating fungus. Further still, it is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Additionally, it would have been obvious to determine suitable concentrations of the ingredients disclosed by the prior art (beta-glucans, glucomannan, endo-1,3(4)-beta-glucanase, mineral clay, calcined diatomaceous earth) through routine experimentation. Likewise, the selection of an appropriate amount of the composition added to animal feed would have been a routine matter of optimizing a result-effective parameter at the time of applicant's invention.

Note that the motivation of adding endo-1,3(4)-beta-glucanase and calcined diatomaceous earth to the Howes composition is to reduce mycotoxins by inhibiting fungal

growth, which prevents immunosuppression from occurring, and thereby augmenting the innate immune system which in turn reduces susceptibility to an infection. However, even if the uses recited in instant claims 1-4 and 28-30 were not disclosed in the references, applicant should note that M.P.E.P. § 2112.01 recites, "Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." See *In re Spada* (citations omitted). Furthermore, M.P.E.P. § 2112 reads, "The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable." Something that is old does not become patentable upon the discovery of a new property, use, or application.

Finally, the references render obvious claims 22-25 since they are product-by-process claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can

only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. “[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

In sum, a holding of obviousness is clearly required.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howes et al., Kessler et al., Kofod et al., and Urman et al. as applied to claims 1-30 above, and further in view of Tangarone et al. (*Applied and Environmental Microbiology*, 1989, 55(1): 177-184)

As discussed above, Howes et al., Kessler et al., Kofod et al., and Urman et al. render claims 1-30 obvious. However, the references do not expressly disclose that beta-1,3(4)-endoglucanohydrolase included in the composition should be produced from submerged

fermentation of *T. longibrachiatum*, as recited in instant claim 22. Though this claim is a product-by-process claim, these limitations are addressed in the following discussion.

Tangarone et al. discloses that beta-1,3(4)-endoglucanohydrolase (E.C. 3.2.1.6) may be produced from a liquid culture of *T. longibrachiatum* (see abstract, page 177, first paragraph, and page 177, "Medium and culture conditions"). Thus, Tangarone et al. teaches the production of beta-1,3(4)-endoglucanohydrolase from a submerged fermentation of *T. longibrachiatum*.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to have used beta-1,3(4)-endoglucanohydrolase produced from submerged fermentation of *T. longibrachiatum*, as described by Tangarone et al.

One would have been motivated to do this since the methods of Tangarone et al. resulted in the purification of active beta-1,3(4)-endoglucanohydrolase. As noted in Kofod et al., *T. longibrachiatum* is known as a source of beta-1,3(4)-endoglucanohydrolase. Thus, a holding of obviousness is clearly required.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howes et al., Kessler et al., Kofod et al., and Urman et al. as applied to claims 1-30 above, and further in view of JP 07184595.

As discussed above, Howes et al., Kessler et al., Kofod et al., and Urman et al. render claims 1-30 obvious. However, these references do not expressly disclose that the beta-glucans and glucomannan obtained from *S. cerevisiae* is obtained by boiling yeast in addition to the autolysis of yeast cell walls, as recited in instant claims 23 and 24. Though these claims are product-by-process claims, these limitations are addressed in the following discussion.

‘595 discloses a feed additive wherein *S. cerevisiae* is autolysed, boiled, and then mixed with a cell wall degrading enzyme. This mixture is then added to animal feed. See the DERWENT abstract (last paragraph of the first page, first paragraph of the second page).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have treated *S. cerevisiae* with the same methods as disclosed by ‘595, and used the resulting yeast cell wall extract in the composition taught by Howes et al. One of ordinary skill in the art would have been motivated to do this since this yeast cell wall extract had been successfully used in ‘595 in an animal feed additive, which was shown to have resulted in “improved aperitive and immunostimulant activities” (see second paragraph on second page of DERWENT abstract). Thus, a holding of obviousness is clearly required.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howes et al., Kessler et al., Kofod et al., and Urman et al. as applied to claims 1-30 above.

As discussed above, Howes et al., Kessler et al., Kofod et al., and Urman et al. render claims 1-30 obvious. However, these references do not expressly disclose that the calcined diatomaceous earth is obtained by calcination at a minimum temperature of 900°C, as recited in instant claim 25. Though this claim is a product-by-process claim, these limitations are addressed in the following discussion.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have conducted the calcination at temperatures other than those disclosed in Urman et al., including 900°C, in order to obtain the calcined diatomaceous earth. The selection of a specific suitable temperature for calcination, including that claimed, clearly would have

been an obvious matter of optimization on the part of the artisan of ordinary skill. Thus, a holding of obviousness is clearly required.

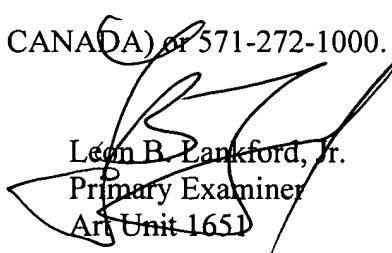
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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